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Open flap debridement and guided tissue regeneration after 10 years in infrabony defects

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Abstract

Objective: Evaluation of the 10-year results after open flap debridement (OFD) and guided tissue regeneration (GTR) therapy of infrabony defects in a randomized controlled clinical trial.

Materials and Methods: In 16 periodontitis patients OFD or polylactide acetyltributyl citrate barriers (GTR; $n = 23$) were assigned randomly to 44 infrabony defects. In a subgroup of 10 patients exhibiting 2 contra-lateral defects each OFD and GTR was assigned to either side (split-mouth). At baseline, 12, and 120 ± 12 months after surgery clinical parameters were obtained.

Results: Fifteen patients (41 defects) were available at 120 months. Twelve and 120 ± 12 months after therapy both groups showed statistically significant ($p < 0.01$) attachment gain (split-mouth: OFD: 12 months: 3.60 ± 2.67 mm; 120 months: 3.65 ± 3.36 mm; GTR: 12 months: 3.50 ± 1.90 mm; 120 months: 2.85 ± 2.24 mm; parallel: OFD: 12 months: 3.47 ± 2.80 mm; 120 months: 3.41 ± 2.75 mm; GTR: 12 months: 3.67 ± 2.11 mm; 120 months: 2.89 ± 2.12 mm). From 12 to 120 months both groups experienced insignificant attachment changes, however, six teeth (two OFD, four GTR) were lost (all for prosthodontic reasons). The study failed to show statistically significant attachment gain differences between both groups after 120 months.

Conclusions: Ten years after OFD and GTR in infrabony defects 35 of 41 teeth were still in place.

Key words: guided tissue regeneration; interproximal infrabony defects; long-term results; open flap debridement; periodontitis; randomized controlled clinical trial

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Open flap debridement (OFD) results predominantly in reparative healing, i.e. the formation of a long junctional epithelium (Zappa 1991, Windisch et al. 2002). The potential of bioabsorbable barrier membranes to facilitate periodontal regeneration has been demonstrated in several histometric studies in animals (Magnusson et al. 1988, Kon et al. 1991, Gottlow 1993, Caffesse et al. 1994) and some histological studies in humans (Zappa 1991, Windisch et al. 2002). After guided tissue regeneration (GTR) therapy using bioabsorbable barriers the majority of clinical studies have observed more favourable results in vertical bony defects (BDs) than after OFD (Murphy & Gunsolley 2003, Needleman et al. 2006). Clinical studies on regenerative therapy of infrabony lesions using bioabsorbable barriers reported results for observation periods of 5 years (Eickholz et al. 2004, Sculean et al. 2004, Mengel et al. 2006, Eickholz et al. 2007, Slotte et al. 2007) and 6–7 years (Stavropoulos & Karring 2004). Results after longer observation periods are scarce (Cortellini & Tonetti 2004, Sculean et al. 2006, Pretzl et al. 2008, 2009). However, in most cases the respective studies do not report an OFD control. Up to now there is only one clinical trial with observation periods of 10 years comparing the results of OFD and regenerative therapy in infrabony defects (Sculean et al. 2008). The hypothesis behind this study is that short-term clinical results reported after OFD are less stable over long-term periods than after GTR.

Thus, the objective of the present randomized controlled clinical trial was (i) to assess and (ii) to compare clinical results 10 years after OFD and GTR therapy using a bioabsorbable barrier (Gottlow 1993, Laurell et al. 1994). The population had been evaluated after 12 months (Ratka-Krüger et al. 2000) already.

Conflict of Interest and Source of Funding

The authors declare that they have no conflict of interests.

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Material and Methods

Patients

Originally in 16 patients (eight female) under periodontal treatment at the Department of Periodontology, Center of Dental, Oral, and Maxillofacial Medicine (Carolinum), Johann Wolfgang Goethe-University Frankfurt/Main a total of 44 infrabony lesions were treated with conventional access flap surgery (OFD). In 23 defects in addition to flap surgery the infrabony defects were isolated using bioabsorbable polylactide acetyltributyl citrate barriers (Guidor Matrix Barrier, Guidor AB, Huddinge, Sweden) (Ratka-Krüger et al. 2000). They ranged in age from 29 to 61 years and had to fulfil the following inclusion criteria:

- diagnosis of severe chronic periodontitis
- presence of two- or three-walled infrabony defects
- probing pocket depth (PPD) at the infrabony defect $\geqslant 5$ mm
- effective individual oral hygiene: approximal plaque index (API) $\leqslant 25\%$ (Lange et al. 1977)
- written informed consent

One hundred and twenty $\pm$ 12 months after surgery all patients who had originally participated in this clinical trial were to be re-examined. After enrolment of the patients the study protocol, risks, benefits, and procedures were explained and informed consent obtained. The study was approved by the Institutional Review Board for Human Studies of the Medical Faculty of the Johann Wolfgang Goethe-University Frankfurt/Main (approval #255/07).

All patients were asked about current and past cigarette consumption. Patients who reported to smoke or had quit smoking for less than 5 years were classified as smokers (Lang et al. 2003). All patients included in this study were then retrospectively tested for the interleukin-1 β-polymorphism using a test kit (GenoType PRT Parodontitis-Risiko-Test, Hain Life Science GmbH, Nehren, Germany). A foam swab was moved over cheek mucosa for 20 s to sample cells and sent for analysis to the laboratory.

Clinical examinations

Clinical examinations have been described in detail before (Ratka-Krüger et al. 2000). Thus, only brief descriptions are provided here. The plaque index (PlI) (Quigley & Hein 1962) and sulcus bleeding index (SBI) (Mühlemann & Son 1971) were assessed at four sites per tooth. PPD and vertical probing attachment levels (PAL-V) were measured to the nearest 1 mm using a calibrated straight, rigid, periodontal probe (PCP 12, Hu Friedy, Chicago, IL, USA) at baseline and 12 months re-examinations (Ratka-Krüger et al. 2000). In 2005 the Department of Periodontology replaced the PCP 12 by the PCPUNC 15 as standard probe. Thus, 120 $\pm$ 12 months after therapy the clinical parameters were assessed (PlI, SBI, PPD, PAL-V) using a simple manual rigid probe (PCPUNC 15, Hu Friedy) all by the same examiner (KN). This examiner had been calibrated and the measurements using both probes had been compared. KN performed replicate measurements in six sites of one tooth of each of 10 patients unrelated to the reported test sample. For one measurement the PCP12 and the other measurement the PCPUNC15 probe were used. Which probe was used first was assigned by random. Between both measurements at least 30 min. had to pass.

Periodontal surgery

For each defect, treatment assignment was made by random. One defect would receive just OFD (control) and another additionally a bioabsorbable polylactide acetyltributyl citrate barrier (Guidor Matrix Barrier) (test). After complete removal of inflammatory granulation tissue, the root surfaces were thoroughly scaled and root planed. The distances from cemento-enamel junction (CEJ) to the most apical extension of the BD (vertical bone level: PBL-V) and the depth of the infrabony component of the defects (INFRA) were measured using the above-mentioned simple manual periodontal probe. In the test group the bony lesion was covered by the barrier, overlapping the margin of the BD by 3 mm. The membrane was adapted to the root surface by a suture around the root trunk. After a periosteal incision the mucoperiosteal flap was repositioned to cover the membrane completely. The flaps were sutured with inter-dental sutures (Gore Tex Suture, ePTFE Nonabsorbable Monofilament, W.L. Gore & Associates, Flagstaff, AZ, USA) (Ratka-Krüger et al. 2000). Surgery was performed by two clinicians: PRK (10 patients) and EN (six patients).

All patients rinsed with a 0.2% chlorhexidine gluconate solution three times a day for 6 weeks after surgery. During this time, all patients had to refrain from individual mechanical plaque control. Sutures were removed 1 week after surgery. Patients were placed on a maintenance schedule including oral hygiene instruction and professional tooth cleaning 3, 6, and 12 months after surgery (Ratka-Krüger et al. 2000). Later on, most patients left supportive periodontal treatment (SPT) at the Department of Periodontology and saw their general dentist for controls. A patient who complied with at least one SPT visit per year at the Department of Periodontology at the Center of Dental, Oral, and Maxillofacial Medicine (Carolinum), Johann Wolfgang Goethe-University Frankfurt/Main was classified to have regular SPT (Kim et al. 2002, Eickholz et al. 2004, Pretzl et al. 2008, 2009).

At the re-examination 120 $\pm$ 12 months after therapy the gingival bleeding index (Ainamo & Bay 1975) and the plaque control record (PCR; O'Leary et al. 1972) were obtained. Further, PBL-V was measured under local anaesthesia using the simple manual rigid probe (PCPUNC15, Hu Friedy) all by the same examiner (KN) (Eickholz & Hausmann 2002).

Statistical analysis

Calibration measurements with the PCP12 and the PCPUNC15 probe were compared using the paired t test. As measures of agreement for the re-examiner calibration we calculated the standard deviation of single measurements (Cohen & Ralls 1988) and the frequency of differences between both measurements.

The main outcome variable for the comparison of the therapeutical effects of test and control was chosen to be stability of PAL-V gained 12 months after therapy, i.e. change of PAL-V from 12 to 120 $\pm$ 12 months after therapy. To describe failure of therapy tooth loss and attachment loss >2 mm from 12 to 120 $\pm$ 12 months was recorded. Bony fill (i.e. change of the distance CEJ/RM to BD) from baseline to 120 $\pm$ 12 months after therapy was considered a secondary endpoint. All other clinical parameters were considered control variables.

The patient was defined as the statistical unit. Thus, for each patient and treatment assignment, the deepest site within a vertical defect at baseline was evaluated and examined after 12 and 120 ± 12 months. All parameters were tested for normal distribution using the Kolmogorov–Smirnov/Lilliefors test. The means at baseline and 12 as well as 120 ± 12 months after therapy were compared by the paired *t* test or the Wilcoxon sign rank test (SBI and PlI only) for test and control.

Originally two types of analysis were performed: A split-mouth analysis for 10 patients contributing 11 pairs of similar contra-lateral defects (Ratka-Krüger et al. 2000). For comparison of test and control treatment, the changes from baseline to 12 as well as 120 ± 12 months later were calculated as differences and the differences for the main outcome variable (PAL-V) between test and control were compared by the paired *t* test. In addition, 95%-confidence intervals of the mean difference between the therapeutical results after 12 as well as 120 ± 12 months were calculated.

OFD and GTR were compared regarding tooth loss and failure (tooth loss plus attachment loss >2 mm from 12 to 120 ± 12 months) using Fisher's exact test.

To include all defects treated in the study a second analysis in parallel group design was performed (Ratka-Krüger et al. 2000). However, several patients contributed more than one defect or more than one pair of defects to the study. Thus, with respect to the patient as statistical unit multilevel regression analyses were performed (Goldstein 1995, Goldstein et al. 2002). For this analysis the basic level ''site'' was nested in the upper level ''patient'' and patient effects on the outcome were assumed to be random. The following influencing factors were entered into analysis to explain the dependent variables PAL-V change from baseline as well as from 12 months to 120 ± 12 months: therapy (OFD/GTR), baseline PPD, and current smoking. Therapy was defined by indicator variables. Statistical analysis was performed using a computer program (Systat™ for Windows version 10.0, Systat Inc., Evanston, IL, USA).

Results

Fifteen patients with 41 infrabony defects that had originally been treated were available for the 120 ± 12 months re-examination. Number and distribution of re-examined defects according to jaw and tooth type are given in Table 1. One patient originally contributing three defects had refused to be re-examined without giving any reasons. A total of six teeth (2 OFD, 4 GTR) in four patients had been extracted between the 12 and 120 ± 12 months re-examination. Prosthodontic considerations were given as explanation for all six teeth (Table 2).

Clinical parameters

Calibration measurements failed to show statistically significant differences for PAL-V measurements (PCP12: 3.17 ± 1.34 mm; PCPUNC15: 3.15 ± 1.36 mm) and for PPD (PCP12: 2.67 ± 0.99 mm; PCPUNC15: 2.61 ± 0.95 mm). Discrepancies between the replicate assessments for PAL-V were all <1.0 mm for all and for PPD <1.0 mm for all but one measurement. The respective standard deviations for single measurements were 0.34 mm (PAL-V) and 0.32 mm (PPD).

Mean and standard deviation of PlI, SBI, and PPD at baseline, 12 as well as 120 ± 12 months after surgery, changes 12 and 120 ± 12 months after surgery for the 10 pairs of defects of the split-mouth design are given in Table 3a and

Table 1. Number and distribution of re-examined defects according to jaw and tooth type (split-mouth)

Type of tooth	Maxillary	Mandibular	Total
Anterior	7 (2)	4 (2)	11 (4)
Premolar	5 (4)	7 (4)	12 (8)
Molar	– (–)	12 (8)	12 (8)
Total	12 (6)	23 (14)	35 (20)

Table 2. Patient characteristics

Patient #	Age	Teeth (extracted teeth in parentheses)		Regular recalls	Number of recalls	GBI/%	PCR/%	Smoking	Interleukin-1β polymorphism
		OFD	GTR						
1	50	32, 37	21, 42	–	0	3	33	Former	–
2	73	36	24, 46*	–	0	9	21	Never	–
3	54	22, 24, 36	14, 12*, 45	+	20	7	15	Never	+
4	66	–	45	+	16	2	22	Never	+
5	65	43, 45	35	–	0	0	63	Never	+
6	64	14	24	+	24	0	26	Former	–
7	49	36	46	–	0	1	65	Active	+
8	61	46	–	–	0	1	61	Active	–
9	61	35	(14)	–	0	0	33	Former	–
10	41	(25), 35	(15), 45, 47	–	0	2	64	Active	+
11	41	41, 46	36	–	0	4	37	Former	+
12	44	(14), 46	(26), 36	–	0	5	87	Former	–
13	53	13	21*, 23	–	0	1	54	Never	–
14	63	–	21	–	0	1	46	Former	–
15†	54	–	(45)	–	0	–	–	Active	+

*>2 mm attachment loss from 12 to 120 ± 12 months.

†Edentulous at re-examination.

+, factor (e.g. regular recalls) present; –, factor absent; GBI, full mouth bleeding score at 10 year re-examination; PCR, full mouth plaque score at 10 year re-examination.

Table 3. Plaque and sulcus bleeding index, probing pocket depths (a) split-mouth and (b) parallel group

	Plaque index		Sulcus bleeding index		Probing pocket depth	
Patients	OFD $n = 10$	polylactide $n = 10$	OFD $n = 10$	polylactide $n = 10$	OFD $n = 10$	polylactide $n = 10$
(a)						
Baseline	0.70 ± 0.48	0.90 ± 0.57	1.10 ± 0.74	1.80 ± 0.63	9.10 ± 2.42	8.65 ± 2.23
12 months	1.00 ± 0.47	1.20 ± 0.42	1.10 ± 0.32	1.30 ± 0.68	5.50 ± 2.42	4.70 ± 1.64
Change	0.30 ± 0.82	0.30 ± 0.82	0.00 ± 0.82	-0.50 ± 1.08	-3.60 ± 2.59	-3.95 ± 2.19
p	0.257	0.257	1.000	0.187	0.002	<0.001
120 months	1.20 ± 0.79	1.20 ± 0.79	1.30 ± 0.68	1.30 ± 0.48	4.70 ± 1.34	4.50 ± 1.35
Change	0.50 ± 0.85	0.30 ± 0.95	0.20 ± 0.79	-0.50 ± 0.97	-4.40 ± 2.84	-4.15 ± 2.47
p	0.096	0.317	0.414	0.132	0.001	<0.001
Change 12 to 120 months	0.20 ± 0.79	0.00 ± 0.82	0.20 ± 0.79	0.00 ± 0.94	-0.80 ± 2.49	-0.20 ± 1.99
p	0.414	1.000	0.414	1.000	0.335	0.758

	Plaque index		Sulcus bleeding index		Probing pocket depth	
Patients Defects	OFD $n = 12$ $n = 17$	polylactide $n = 12$ $n = 18$	OFD $n = 12$ $n = 17$	polylactide $n = 12$ $n = 18$	OFD $n = 12$ $n = 17$	polylactide $n = 12$ $n = 18$
(b)						
Baseline	0.82 ± 0.64	1.11 ± 0.83	1.24 ± 0.66	1.67 ± 0.59	8.77 ± 2.22	8.69 ± 1.92
12 months	1.24 ± 0.66	1.22 ± 0.43	1.12 ± 0.33	1.22 ± 0.55	5.06 ± 2.30	4.56 ± 1.65
Change	0.42 ± 0.80	0.11 ± 1.08	-0.12 ± 0.82	-0.45 ± 0.92	-3.71 ± 2.85	-4.14 ± 2.00
p	0.053	0.642	0.480	0.065	< 0.001	<0.001
120 months	1.06 ± 0.83	0.83 ± 0.79	1.29 ± 0.59	1.17 ± 0.38	4.35 ± 1.22	4.44 ± 1.42
Change	0.24 ± 0.83	-0.28 ± 1.07	0.06 ± 0.83	-0.50 ± 0.79	-4.41 ± 2.37	-4.25 ± 2.44
p	0.249	0.284	0.763	0.020	<0.001	<0.001
Change 12 to 120 months	-0.18 ± 0.79	-0.39 ± 0.92	0.17 ± 0.73	0.06 ± 0.73	-0.71 ± 2.49	-0.11 ± 1.91
p	0.439	0.088	0.317	0.739	0.236	0.808

for the 35 defects of the parallel group design are given in Table 3b. Twelve and 120 months as well as from 12 to 120 months after surgery OFD and GTR failed to show statistically significant changes of PlI as well as SBI (Table 3). Twelve and 120 months after surgery statistically significant PPD reductions were assessed for both test and control ($p < 0.005$; Table 3). From 12 to 120 months small insignificant PPD decrease was observed in both groups (Table 3).

Mean and standard deviation of PAL-V at baseline, 12 as well as 120 ± 12 months after surgery, changes 12 and 120 ± 12 months after surgery, and differences between test and control for the 10 pairs of defects of the split-mouth design are given in Table 4a and for the 35 defects of the parallel group design are given in Table 4b. Twelve and 120 months after surgery statistically significant PAL-V gains were assessed for both test and control ($p < 0.01$; Table 4). From 12 to 120 months average PAL-V stability was observed in both groups (Table 4). The study observed neither for the split-mouth nor for the parallel group design statistically significant differences between OFD and GTR regarding PAL-V at baseline, 12, and 120 ± 12 months after surgery as well as changes 12 and 120 ± 12 months after surgery (Table 4). Over all split-mouth and parallel group analyses lead to similar results. Table 4c gives a frequency distribution of PAL-V gain for all defects. Multilevel regression analysis identified current smoking to negatively influence and baseline PPD to positively influence PAL-V gain from baseline to 120 months, whereas therapy (OFD/GTR) failed to show a statistically significant effect (Table 5a). Long-term stability (PAL-V change from 12 to 120 months) was only associated with baseline PPD (Table 5b). However, a total of three defects in the GTR group showed attachment loss of more than 2 mm from 12 to 120 months (Table 2). Six additional test teeth were missing at the 120 months re-examination in four patients (2 OFD, 4 GTR) all due to prosthodontic reasons (Table 2). None of the patients who lost test teeth complied with regular SPT. Two of these patients were active and two former smokers, two were positive for the IL-1 polymorphism (Table 2). Neither regarding ''tooth loss'' ($p = 0.668$), nor regarding ''failure'' ($p = 0.140$) Fisher's exact test revealed significant differences between OFD and GTR.

Bone parameters

Mean and standard deviation of PBL-V at baseline and 120 ± 12 months after surgery and changes 120 ± 12 months after surgery, as well as differences between test and control for the 10 pairs of defects of the split-mouth design and for the 35 defects of the parallel group design are given in Table 6. One hundred twenty months after surgery statistically significant PBL-V gains were assessed for both test and control in the parallel group analysis ($p < 0.05$; Table 6). The split-mouth analysis revealed statistically significant bony fill only for the OFD group ($p = 0.011$; Table 6). The analysis failed to reveal statistically significant differences between both groups (Table 6).

Discussion

The majority of studies on GTR-therapy of infrabony defects have reported more favourable clinical results after GTR than after OFD (Murphy & Gunsolley 2003, Needleman et al. 2006). For the sample investigated in the present long-term evaluation 12 months after OFD and GTR no statistically significant differences could be reported between both

Table 4a. Vertical probing attachment level (split-mouth)

	Vertical probing attachment level		*p*
Patients	OFD $n = 10$	polylactide $n = 10$	
Baseline	9.90 ± 2.61	9.20 ± 1.81	0.532
12 months	6.30 ± 2.54	5.50 ± 1.83	0.564
Change	3.60 ± 2.67	3.50 ± 1.90	0.895
p	0.002	<0.001	
120 months	6.25 ± 2.40	6.35 ± 1.33	0.853
Change	3.65 ± 3.36	2.85 ± 2.24	0.530
p	0.007	0.003	
Change 12–120 months	0.05 ± 2.61	− 0.65 ± 2.08	0.531
95% confidence interval	− 1.82 to 1.92	− 2.14 to 0.84	
p	0.953	0.349	

Table 4b. Vertical probing attachment level (parallel group)

	Vertical probing attachment level		*p*
Patients Defects	OFD $n = 12$ $n = 17$	polylactide $n = 12$ $n = 18$	
Baseline	9.47 ± 2.27	9.17 ± 1.51	0.647
12 months	6.00 ± 2.45	5.50 ± 1.87	0.506
Change	3.47 ± 2.80	3.67 ± 2.11	0.818
p	<0.001	<0.001	
120 months	6.06 ± 1.85	6.28 ± 1.24	0.685
Change	3.41 ± 2.75	2.89 ± 2.12	0.535
p	<0.001	<0.001	
Change 12–120 months	− 0.06 ± 2.44	− 0.78 ± 1.93	0.344
95% confidence interval	− 1.82 to 1.92	− 2.14 to 0.84	
p	0.922	0.106	

Table 4c. Frequency distribution of vertical attachment gain at 12 and 120 ± 12 months

	OFD (17 defects) (%)		Polylactide (18 defects) (%)	
	12 months	120 ± 12 months	12 months	120 ± 12 months
<2 mm	23.5	23.5	16.7	27.8
⩾2–<4 mm	23.5	17.6	22.2	38.9
⩾4–<6 mm	29.5	41.3	38.9	22.2
⩾6 mm	23.5	17.6	22.2	11.1

Table 5. Multilevel regression analyses

	Estimate	Standard error	*Z* value	*p*
(a) Dependent variable: Change of PAL-V from baseline to 120 ± 12 months 14 patients/35 infrabony defects				
Intercept	− 4.775	1.160	− 4.118	<0.001
Open flap debridement	0.419	0.485	0.869	0.385
Baseline probing pocket depth	0.908	0.127	7.166	<0.001
Active smoker	− 1.423	0.760	− 1.873	0.061
(b) Dependent variable: Change of PAL-V from 12 to 120 ± 12 months 14 patients/35 infrabony defects				
Intercept	− 4.912	1.545	− 3.179	0.001
Open flap debridement	0.647	0.586	1.103	0.270
Baseline probing pocket depth	0.500	0.170	2.941	0.003

treatments (Ratka-Krüger et al. 2000). Twelve months after OFD in two- and three-walled infrabony defects with an infrabony component of 6.0 mm they reported better PAL-V gain (split-mouth: 3.60 mm; parallel groups: 3.47 mm) than other authors have reported after OFD of less favourable defects [1.6 mm (INFRA: 3.9 mm; Cortellini et al. 1998); 1.6–1.8 mm (INFRA: 3.6–4.3 mm; Pontoriero et al. 1999; 1.3 mm (INFRA: 4.1 mm; Zybutz et al. 2000)] and after treatment of similar defects [2.6 mm (INFRA: 6.3 mm; Cortellini et al. 2001)]. Twelve months after GTR using polylactide acetyltributyl citrate in infrabony defects (INFRA: 6.8 mm), this study observed reasonable PAL-V gain (split-mouth: 3.50 mm; parallel groups: 3.67 mm). Twelve months after use of polylactide acetyltributyl citrate for GTR treatment of similar defects other authors have reported similar [3.5 mm (INFRA: 6.3 mm; Cortellini et al. 2001)] and less favourable PAL-V gain [2.4 mm (INFRA: 7.0 mm; Zybutz et al. 2000)]. Treating less favourable defects with polylactide acetyltributyl citrate other studies reported less favourable PAL-V gain [3.0 mm (INFRA: 4.0 mm; Cortellini et al. 1998)] and similar PAL-V gain [3.4 mm (INFRA: 4.2 mm; Pontoriero et al. 1999)]. The only study that to our best knowledge reports also 10 years results after GTR using polylactide acetyltributyl citrate found more favourable PAL-V gains of 4.06 mm after 12 and less stability with remaining PAL-V gains of 2.44 mm after 120 ± 6 months for infrabony defects with INFRA = 5.65 mm (Pretzl et al. 2009). However, Cortellini et al. observed more favourable PAL-V gains in defects with less favourable or similar baseline infrabony defect depth: titanium-reinforced ePTFE: 5.3 mm (INFRA: 5.5 mm; Cortellini et al. 1995); ePTFE: 5.2 mm (INFRA: 7.0 mm; Cortellini et al. 1996b); other bioabsorbable barriers: 4.6 mm (INFRA: 7.2 mm; Cortellini et al. 1996b). Characteristics of infrabony defects have been shown to influence periodontal healing (Cortellini et al. 1998, Pontoriero et al. 1999, Klein et al. 2001). The morphology of infrabony defects in this study was particularly favourable: two- and three-wall defects with a quite deep infrabony component. Thus, they were likely to respond well to surgery in general as well as to OFD. It is not surprising to see better results for OFD in this study than in others because the defects treated in this study were more favourable than in most other studies comparing OFD and GTR. The only study reporting results after OFD in similarly favourable defects was a multicentre trial (Cortellini et al. 2001). We may speculate that more consistent treatment of only 2

Table 6. Distances from cemento-enamel junction to bony defect

	Cemento-enamel junction to bony defect (split-mouth)			Cemento-enamel junction to bony defect (parallel group)		
	OFD $n = 10$	polylactide $n = 10$	p	OFD $n = 17$	polylactide $n = 18$	p
Baseline	10.25 ± 2.62	9.80 ± 3.46	0.755	9.91 ± 2.35	9.72 ± 2.61	0.822
120 months	8.10 ± 2.30	8.50 ± 1.86	0.581	7.88 ± 1.94	8.03 ± 1.76	0.818
Change	2.15 ± 2.15	1.30 ± 3.47	0.493	2.03 ± 2.30	1.69 ± 2.91	0.707
p	0.011	0.267		0.002	0.024	

surgeons at the same centre (Ratka-Krüger et al. 2000) may have contributed to remarkably favourable results after OFD compared with the multicenter trial with many different operators at different locations (Cortellini et al. 2001). Further, these favourable defects responded as good or better to GTR than other authors have reported after use of polylactide acetyltributyl citrate barriers (Zybutz et al. 2000, Cortellini et al. 2001). Why did the defects fail to respond to GTR better than to OFD? Perhaps the high amount of defects at posterior teeth may explain this observation. The application of barrier membranes is less easy at posterior than at anterior sites. The present study provided maintenance at 3 and 6 months after surgery (Ratka-Krüger et al. 2000). GTR-treated sites may have taken benefit from more intense or frequent maintenance between baseline and 12 months in other studies [monthly (Cortellini et al. 1998), week 11, 6, and 9 months (Cortellini et al. 2001)]. The proportion of nonsmokers in this study (73%) is similar to others who reported less PAL-V gain after OFD (69.6%; Cortellini et al. 2001). Further, self-supporting infrabony defects (deep three-wall defects) from a clinical point of view are likely to respond clinically favourably already to OFD. This kind of defects does not take much additional clinical benefit from regenerative procedures. However, despite similar clinical results we expect reparation after OFD and regeneration after GTR. However, reparation and regeneration cannot be distinguished by this clinical study.

With the knowledge that GTR provides periodontal regeneration and OFD results in reparative healing we postulated that GTR is superior to OFD. Observing in this study that PAL-V gains 12 months after surgery are the same after OFD and GTR, we generated the hypothesis that long-term stability of PAL-V should be better after GTR than after OFD. However, this hypothesis could not be confirmed by the results of the 120 months re-examination of the present sample. PAL-V was stable on average in both groups. The few studies that report on stability 10 years after GTR therapy observed moderate PAL-V loss of <2.0 mm (Pretzl et al. 2008, 2009). This is in accordance with the PAL-V loss observed in this study 120 ± 12 months after therapy in both groups (OFD/GTR).

However, looking only at means does not account for the six teeth missing at the 120 ± 12 months re-examination (OFD: 2; GTR: 4). According to the patients' self-report all six teeth were extracted due to prosthodontic considerations alio loco and thus may not count as periodontal complications. Also mean PAL-V loss observed in both groups does not fully describe periodontal stability. We defined a defect experiencing PAL-V loss from 12 to 120 ± 12 months of more than 2 mm as instable site. Failure from 12 to 120 ± 12 months is not distributed equally over all patients. Cortellini et al. had revealed patient characteristics like irregular attendance of SPT, smoking, and a general tendency to attachment loss during SPT (loser patients) to account for most attachment losses (Cortellini et al. 1996a). Other authors had tried to explain this tendency to attachment loss by the presence of the interleukin-1 gene polymorphisms (De Sanctis & Zucchelli 2000). However, most studies investigating the IL-1 polymorphism as putative risk factor for attachment loss after periodontal regeneration failed to find a correlation (Cortellini & Tonetti 2004, Eickholz et al. 2007). Taking the instable defects and lost teeth together failure was observed in seven defects treated in the GTR group in seven different patients and only in two defects of the OFD group in two patients who each had lost also a GTR tooth. Patients 10 and 12 each lost one tooth in either group (OFD/GTR) (Table 2). Patient 10 failed to attend SPT regularly, showed ineffective oral hygiene (PCR = 64%), was current smoker, and IL-1 positive. Patient 12 also exhibited erratic SPT and ineffective oral hygiene (PCR = 87%) at the re-examination but no other considered risk factors. All but one patient suffering instability in at least one defect failed to attend SPT regularly. However, multilevel analysis failed to identify ineffective oral hygiene, current smoking, IL-1 polymorphism or regular SPT to influence PAL-V stability. Only 32 (78%) of all re-examined defects (41) could be kept stable over 10 years. However, total failure (tooth loss) was observed in only six of 41 defects (15%) after 10 years. The definition of regular SPT uses a low threshold (at least one SPT visit per year). This low threshold perhaps is the reason that ''regular SPT'' could not be identified as influencing factor by multilevel analysis. It may be speculated that SPT visits every 3–6 months (Cortellini & Tonetti 2004) may have made a difference and may have improved success.

There is an obvious dilemma in the effort to achieve high intra- and inter-examiner reproducibility and obtaining long-term results. Nine years after the short-term re-examinations (12 months) have been accomplished even the reproducibility of the original examiners may not be the same anymore. Thus, a comparison of the original examiner to the examiner of the 120 ± 12 months re-examination (KN), e.g., by replicate measurements is unlikely to resolve this problem. However, this issue applies to all long-term observations.

The barrier membrane used in this clinical trial has recently been reintroduced to market. Thus, the results of this study may be particularly valuable to the clinician to decide what particular membrane material should be used. Further, the study adds information to the small data pool of 10 years results after regenerative periodontal therapy.

The sample size (split-mouth: 10 patients, 10 pairs of defects; parallel group: 12/12 patients, 17/18 defects) of this study was too small to show equivalence of both surgical techniques with sufficient test power after 120 ± 12 months. For a clinically relevant difference ($\delta > 1.0$ mm) between OFD and GTR, a type I error $\alpha < 0.05$ and a standard deviation of the difference between test and control for change of PAL-V from 12 to 120 ± 12 months of

$s = 3.40$ mm a test power of 13.3% (split-mouth) and standard deviation of 2.44 mm a test power of 21.3% (parallel group) was calculated, respectively. However, a difference in PAL-V between test and control from 12 to 120 ± 12 months of 0.60 mm (split-mouth) and 0.62 mm (parallel group) may be looked upon as clinically irrelevant.

Within the limitations of the present study we may draw the following conclusions:

- The vertical attachment gains achieved either by OFD and GTR therapy using bioabsorbable barriers could be maintained stable up to 10 years after surgery in 32 of 41 (78%) deep two- and three-wall infrabony defects.

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Supporting Information

Additional supporting information may be found in the online version of this article:

Table S1. Checklist of items to include when reporting a randomized trial (56–58).

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Clinical Relevance

Scientific rationale for the study: Most clinical studies comparing OFD and GTR in infrabony defects report short-term results. However, the ultimate goal of periodontal therapy is long-term retention of teeth in a functional and aesthetic state. Thus, information on the long-term stability of results after OFD and GTR therapy is required to judge the benefit of these techniques.

Principal findings: Ten years after OFD and GTR in infrabony defects 9 of 41 teeth available for re-examination were lost or had experienced attachment loss >2 mm.

Practical implications: Treatment results assessed 12 months after therapy with OFD and bioabsorbable barriers may be maintained stable in 78% of all treated defects over 10 years.